



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> :  A61B 19/00	A1	(11) International Publication Number: <b>WO 99/63901</b>  (43) International Publication Date: 16 December 1999 (16.12.99)
(21) International Application Number: PCT/US99/12722  (22) International Filing Date: 7 June 1999 (07.06.99)		(74) Agents: LEVY, David, J. et al.; Glaxo Wellcome Inc., Five Moore Drive, P.O. Box 13398, Research Triangle Park, NC 27709-3398 (US).
(30) Priority Data: 60/088,400 8 June 1998 (08.06.98) US		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 60/088,400 (CIP) Filed on 8 June 1998 (08.06.98)		
(71) Applicant (for all designated States except US): GLAXO GROUP LIMITED [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).		
(72) Inventors; and (75) Inventors/Applicants (for US only): DIMSDALE, Todd, Anthony [US/US]; Glaxo Wellcome Inc., Five Moore Drive, P.O. Box 13398, Research Triangle Park, NC 27709-3398 (US). JONES, Donna, Elizabeth [US/US]; Glaxo Wellcome Inc., Five Moore Drive, P.O. Box 13398, Research Triangle Park, NC 27709-3398 (US).		Published With international search report.
<p><b>(54) Title:</b> DISEASE MANAGEMENT/TRAINING SYSTEM AND METHOD</p> <p><b>(57) Abstract</b></p> <p>This invention is a computer implemented disease management, and training method. The method can be used to training asthma patients self-management skills. The method includes creating, storing, processing the relevant data (101) to a patient's condition, and producing output reports (141) to health care personnel.</p>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		

## DISEASE MANAGEMENT/TRAINING SYSTEM AND METHOD

DescriptionPriority Application Information

5        This application claims the benefit of U.S. Provisional patent application No. 60/088,400, filed June 8, 1998 the disclosure of which is incorporated herein by reference in its entirety.

Technical Field

10       The present invention relates to an interactive computer implemented system for the training in and management of diseases. Specifically, the present invention relates to an interactive computer implemented system for the training in and management of an individualized asthma care program.

15

Background Art

One problem with current health care as it relates to disease management is that afflicted individuals many times do not realize they are suffering an episode related to their disease until such an episode has completely manifested itself upon the individual. These occurrences often necessitate emergency room visits or extended hospital stays. Emergency room visits and hospital stays are among the costliest events in the healthcare industry which, in turn, keep health care insurance costs at all time high levels. Moreover, afflicted individuals suffer greater discomfort during such events.

If patients could be taught to understand and manage their condition to the extent that oncoming episodes can be recognized and dealt with at the earliest possible stage, then the patient can often times avoid an emergency room visit or hospital stay. The benefit is twofold. First, the patient can start receiving appropriate treatment (e.g., medication, behavior modification) before the episode has progressed to the point of requiring immediate medical attention. Second, the health care industry may not need to expend the costly resources required to attend to a patient suffering from a full blown episode.

The key to such an undertaking is linking patients and health care professionals in such a way that fosters a greater understanding on the part of the patient with respect to their affliction and that gives the ability to systematically monitor a host of disease contributing factors.

- 5 One possible system or methodology of achieving the benefits described above involves a computer implemented system of managing patient data which is designed to educate a patient with respect to their disease and track their progress as it pertains to their utilization of health care resources over a period of time. Elements of such a system would include gathering  
10 extensive demographic data about the patient. Profiling the patient data to identify environmental symptom impact data as it relates to their specific affliction, and educating the patient to avoid or curtail high risk activities and situations. For instance, in the case of asthma, a patients level of suffering is affected by environmental stimuli such as dust, smoke, humidity, pets, etc.  
15 Educating a patient to recognize certain disease triggers can help the patient modify their environment to minimize or even completely eliminate the presence of such triggers. The system goes beyond education, however. Even under ideal conditions episodes can occur. In such instances it is critical for the patient to know precisely how to react. One helpful tool is a disease  
20 action plan which spells out steps to take during episodic events. Such plans are formulated usually with the participation of the patient's physician. These plans include, *inter alia*, medication data, emergency phone data, and objective evaluation or situation assessment data.

- What is needed is a tool for implementing the aforementioned goals  
25 which provides the patient with the information and management skills needed to reduce serious events while giving health care professionals an objective outcomes driven tool for measuring the patient's utilization of health care resources over time. The goal being to reduce the frequency of a patient's need for emergency medical attention and/or hospitalizations.

Disclosure of the Invention

The present invention includes systems, methods, and computer program products for an interactive computer implemented system for the training in and management of diseases. The present invention integrates data collection, management training, identification of environmental factors, and administrative functions from a variety of sources including disease sufferers (e.g., patients or participants), physicians (or other health care providers), and training personnel. At the center of the data collection and management system is a computer program that processes input data from the variety of sources and provides specific output to one or more sources. The output is designed to measure, monitor, and promote a participant's progress in managing their condition and also to help identify areas of strengths and weaknesses.

In an exemplary embodiment of the invention, the disease of asthma is illustrated. To start, a group of potential program participants that have exhibited significant asthma related encounters are identified. Each of the potential participants is contacted, either in person or by phone, and given an explanation of the management care program and asked if they are interested in participating. If successfully recruited, each participant's physician is notified and informed of the program's particulars and their role in same.

The first part of the program calls for a meeting between a program coordinator (hereinafter "trainer") and the participant. The purpose of this meeting is to gather, *inter alia*, personal, demographic, physical, and environmental data about each participant. This is done via a set of surveys or questionnaires that each participant completes. This first visit also includes educational discussions on asthma and tools for treating and/or managing asthma. The initial visit is typically concluded with the trainer scheduling a subsequent visit with the participant.

Following the initial visit, the gathered data is input into a central database either directly or through a dial-up modem connection where it is

Figure 6 illustrates the hierarchical menu structure of an individualized asthma care training computer program.

Best Mode for Carrying Out the Invention

The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

As will be appreciated by those skilled in the art, the present invention may be embodied as a method, data processing system, or computer program product. Accordingly, the present invention may take the form of an entirely software embodiment or an embodiment combining software and hardware aspects. Furthermore, the present invention may take the form of a computer program product on a computer-readable storage medium having computer-readable program code means embodied in the medium. Any suitable computer readable medium may be utilized including hard disks, CD-ROMs, optical storage devices, or magnetic storage devices.

To the extent that the present invention is described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to the invention, it will be understood that each block of the flowchart illustrations, and combinations of blocks in the flowchart illustrations, can be implemented by computer program instructions. These computer program instructions may be loaded onto a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the

inhaler (MDI) data, nebulizer data, environmental assessments, specific trigger discussions, and lifestyle discussions. Computer implemented program administration includes visit scheduling, participant recruitment, participant enrollment, participant disenrollment, maintaining of physician profiles, numerous reporting functions, maintaining a list of allergy control companies, supply ordering, and data exchange between the central database and trainers.

It is an object of the invention provide a computer implemented system to aid in the training of disease sufferers in the management of their disease condition.

It is a further object of the invention to reduce the occurrence of hospitalization stays and emergency room visits resulting from disease events by providing educational and management skills to sufferers which may prevent or minimize the severity of disease symptoms.

Further objects of the invention will become apparent to those skilled in the art with reference to the accompanying figures and written description below.

#### Brief Description of the Drawings

**Figure 1** is a system overview illustrating the chronic disease management/training system and method;

**Figure 2** is a block diagram illustrating the procedure for identifying and enrolling qualified participants in the chronic disease management program;

**Figure 3** is a block diagram illustrating the events occurring during the initial visit between a program trainer and a program participant;

**Figure 4** is a block diagram illustrating the significance of a chronic disease management action plan;

**Figure 5** is a block diagram illustrating the events occurring during subsequent visits between a program trainer and a program participant; and

Figure 6 illustrates the hierarchical menu structure of an individualized asthma care training computer program.

Best Mode for Carrying Out the Invention

The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

As will be appreciated by those skilled in the art, the present invention may be embodied as a method, data processing system, or computer program product. Accordingly, the present invention may take the form of an entirely software embodiment or an embodiment combining software and hardware aspects. Furthermore, the present invention may take the form of a computer program product on a computer-readable storage medium having computer-readable program code means embodied in the medium. Any suitable computer readable medium may be utilized including hard disks, CD-ROMs, optical storage devices, or magnetic storage devices.

To the extent that the present invention is described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to the invention, it will be understood that each block of the flowchart illustrations, and combinations of blocks in the flowchart illustrations, can be implemented by computer program instructions. These computer program instructions may be loaded onto a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the

instructions which execute on the computer or other programmable data processing apparatus create means for implementing the functions specified in the flowchart block or blocks. These computer program instructions may also be stored in a computer-readable memory that can direct a computer or other programmable data processing apparatus to function in a particular manner, such that the instructions stored in the computer-readable memory implement the function specified in the flowchart block or blocks. The computer program instructions may also be loaded onto a computer or other programmable data processing apparatus to cause a series of operational steps to be performed on the computer or other programmable apparatus to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide steps for implementing the functions specified in the flowchart block or blocks.

Accordingly, blocks of flowchart illustrations support combinations of means for performing the specified functions, combinations of steps for performing the specified functions and program instruction means for performing the specified functions. It will also be understood that each block of flowchart illustrations, and combinations of blocks in flowchart illustrations, can be implemented by special purpose hardware-based computer systems which perform the specified functions or steps, or combinations of special purpose hardware and computer instructions.

#### SYSTEM OVERVIEW

Referring now to **Figure 1**, a system overview of the disease management/training system and method is illustrated. A database 100 acts as the repository for raw participant data 101 as well as program participant data. Raw participant data comprises demographic data about individuals who meet certain criteria and qualify as candidates for a disease management

program. The raw participant data 101 is downloaded to a local computer 110 used by qualified trainers and, depending on the nature of the disease, certified to some degree of proficiency with respect to the disease. There can be multiple trainers (T1-T4) each responsible for multiple participants (P1-P4). An exemplary data structure is shown within the database 100 in which four (4) trainers are illustrated as having four (4) participants. Each trainer has his own file/data directory within the database 100 in which each participant has his own file/data subdirectory. Typically, trainers interact with the database 100 from their local computer 110 via a dial-up modem connection 120.

It is important that the trainer's local computer 110 continually be updated and synchronized with respect to the data in the database 100. Accordingly, the trainer's computer and the database may exchange trainer/database synchronization information 121.

The trainer, with computer 110, maintains contact with participant(s) 130 and physician(s) 140 for the purpose of collecting and disseminating management care program data. For example, in the illustrated embodiment, the computer 110 may transmit or generate post visit reports 141 to or for the physician 140. The participant 130 may input survey data 142 and visit data 143 into the computer 110. The survey data 142 and the visit data 143 may be transmitted from the computer 110 to the database 100.

Although in the illustrated embodiment the database 100 is separate from the computer 110, the present invention is not limited to such an embodiment. For example, in an alternative embodiment, the database 100 may be resident on the computer 110. The database 100 may be located on a magnetic storage medium associated with the hard disk drive of the computer 110, on an optical storage medium associated with the optical disk drive of the computer 110 or any other storage medium associated with the computer 100.

In such an embodiment, the disease management program may write data to and receive data from the database by accessing local storage media.

Figures 2-5 are block diagrams illustrating exemplary steps involved in a disease management program and the data processing that takes place. Referring now to **Figure 2**, in step 200, raw data is obtained by a program trainer pertaining to potential candidates for a disease management program. This data typically includes demographic data identifying potential program participants and their suitability for a particular disease program. The data may originate from an outside source but is downloaded from the database to a trainer's local computer. In step 210, a trainer will contact potential candidates in order to recruit and enroll them into a particular disease management program. In step 220, for each enrolled participant, a corresponding program announcement letter is sent to that participant's physician describing the program.

Referring now to **Figure 3**, in step 300, upon enrollment of a participant, the trainer schedules an initial visit with the participant. In step 310, during the initial visit, the trainer collects data from the participant mostly in the form of surveys. The surveys are administered via a software based interactive set of windows in which the participant is asked a series of questions. A typical initial visit is conducted in the participant's home and comprises a detailed program introduction explaining the procedures of the program, a review of the participant's demographic data, administration of the initial surveys, a review of the participant's current medications, a physical assessment of the participant, a review of the disease itself, and an introduction to management tools and other educational data. Next, in step 320, the survey data is input into the trainer's local computer for subsequent uploading to the database. When the database is resident on the trainer's computer, the data may be written directly to the appropriate storage medium, such as a magnetic disk. In

step 330, the data is also processed locally and a post-visit report is generated. In step 340, the post-visit report is intended for and sent to the participant's physician for review. The initial visit usually concludes with a discussion of participant goals for a next visit. Lastly, in step 350, a subsequent visit is scheduled between the trainer and participant. Subsequent visits can either be in person or telephonic.

Referring now to **Figure 4**, the trainer contacts the participant's physician and, in step 400, inquires as to whether the participant has a disease action plan in place. In step 410, if the trainer does not have a disease action plan in place, the trainer will send a form 410 to the participant's physician, explaining the purpose of the disease action plan, and asking the physician to provide any missing information. The plan identifies a patient's "zones", and what to do in each of the zones. In addition, the plan provides essential phone numbers (relatives/physician/ambulance) and other pertinent information. It is the physician's decision to send the action plan to, and initially discuss the action plan with, the participant. Once the trainer receives the completed action plan, the trainer will also review the action plan with the participant. Subsequently, the trainer will review with the participant his adherence to the action plan, and the trainer will assist the participant in communicating issues around the action plan to the physician.

A disease action plan for asthma is discussed below as an example. Asthma is a highly variable disease. Patients can go from asymptomatic exhibiting normal lung function to highly symptomatic exhibiting severely restricted airflow in a matter of minutes in response to a trigger. Patients need to be instructed by their physician what to do at the onset of such instances. In order to be effective, action plans should be in an easy to understand written format. Such plans are commonly referred to as Asthma Control Plans or Asthma Action Plans. The National Asthma Education Program of the

National Heart, Lung and Blood Institute recommend providing a written plan to all moderate and severe asthmatics comprising the following components:

- Current medications and dosages
- Warning signs and symptoms of impending exacerbations
- Peak expiratory flow rate measurements
- Instructions for use of asthma medications during exacerbations
- Instructions (including telephone numbers) for when and who to call

Referring now to **Figure 5**, subsequent visit procedures are detailed.

Generally, in step 500, a visit commences by discussing disease related events, if any, that have occurred since the last visit. The discussion may also include any goal achievements from the last visit. In step 510, additional data is collected during the visit using interviews and more interactive surveys. Many of the same topics discussed in the initial visit are discussed again including medications, disease reviews, management tools, and physical and environmental assessments. In step 530, collected data is forwarded to the database and the trainer's computer is then updated or synchronized with the database in order to ensure the integrity of the gathered program data. Synchronization is generally done on a daily basis. In step 540, newly acquired data is processed and post-visit reports are generated. In step 550, the post-visit reports are forwarded to the participant's physician for review. In step 560, further visits are scheduled on an as needed basis, largely at the discretion of the trainer.

One exemplary embodiment of the invention implements the above described system and methodology for the training in and management of the disease of asthma. A comprehensive computer implemented program is described which facilitates and manages all of the above described data collection and processing functions providing a measurable outcome for evaluating the health maintenance progress of individuals participating in such

12.

a program as well as the effectiveness of the program overall as it pertains to improving the health maintenance of participants while decreasing the costs associated with emergency room visits and extended hospitalizations. Outcomes are measured by comparing each participant's progress or condition from report to report.

A windows driven graphical user interface computer program typically resides on a trainer's local computer, which, in most cases, is a laptop type computer for portability. The program is a compilation of data intake, data processing, network communication, and output generating modules interdependent on and communicating with one another.

**Figure 6** illustrates a hierarchical menu structure of an example of an individualized asthma care training (IACT) program. Each of the boxes performs the function described via a set of standard windows drop down menus having standard point and click capabilities. That is, through the use of a mouse (or other similar input device), a trainer can access any one of the boxes illustrated in **Figure 6**. At the top is the IACT Main Menu 1000 which represents the starting point upon execution of the IACT program. There are seven (7) top-level functions including FILE 1002, PARTICIPANTS 1004, SCHEDULE 1006, REPORTS 1008, UTILITIES 1010, POST-VISIT 1012, and HELP 1014. Each of the seven (7) top level functions possesses one or more sub-functions related in some way to its corresponding top-level function.

Throughout the various screens the trainer/user will often face a set of selectable buttons generally used to advance or guide the trainer through the various processes. In particular, the set of "Cancel", "Back", "Next", and "Finish" is used quite often. "Cancel" allows the trainer to escape from the current process and generally return to the preceding process or function. "Back" transfers the trainer to the previous screen of the current process. "Next" advances the trainer to the next step of the current process. "Finish" is

used to complete the current process and is typically only actionable on the last screen of the current process. Whenever one of these buttons is not a selectable option from the current screen it will appear faded out. If the trainer attempts to select a shaded out button nothing will occur. For instance, the trainer will not be able to select the "Back" button from the first screen of a given process, nothing will happen since there is no previous screen to go to.

Another oft used icon is the "close" icon which appears on numerous screens, usually in the lower right portion of the screen. Selecting or clicking the close icon has the general effect of closing the current window or screen and returning the user to the previous window or screen.

Each top-level function is now discussed in greater detail.

#### FILE

Under the FILE function 1002, there is an Exit sub-function 1016 which allows the trainer to close or shut down the IACT program from the current session.

#### PARTICIPANTS

The PARTICIPANTS 1004 function manages many of the interactions between trainers and participants. Its sub-functions include Recruit 1018, Disenroll 1020, Status Report 1022, Personal Contact 1024, Telephone Contact 1026, and Resume Visit 1028. The Recruit sub-function 1018 presents a list of candidates for the asthma care training and management program and demographic data associated with each candidate. As will be more fully described later, the trainer contacts these candidates in hope of enrolling them in an IACT program. The Disenroll sub-function 1020 serves to remove active participants from an IACT program. The Status Report sub-function 1022 provides the current status of a selected participant. The Personal Contact

sub-function 1024 provides the data and procedures necessary to conduct a personal visit. The Telephone Contact sub-function 1026 provides the data and procedures necessary to conduct a telephone visit. The Resume Visit sub-function 1028 allows a user/trainer to resume a previous visit, either personal or telephone, that was interrupted or not completed.

#### SCHEDULE

The SCHEDULE function 1006 organizes and manages a trainer's daily, weekly, and monthly schedule. Its sub-functions include Edit 1030, View Schedule For This Week 1032, View Schedule For This Month 1034, View Schedule For Any Two Dates 1036, and To Do List 1038. The Edit sub-function 1030 allows the trainer to edit his schedule in order to make, change, or delete appointments with participants. The View Schedule For This Week sub-function 1032 permits the trainer to view his schedule for the upcoming week. The View Schedule For This Month sub-function 1034 permits the trainer to view his schedule for the upcoming month. The View Schedule For Any Two Dates sub-function 1036 permits the trainer to view his schedule starting and ending on selected dates. Lastly, the To Do List sub-function 1038 provides a note or scratch pad where the trainer can make informal notes to remind himself of tasks that need to be completed and the status of each task.

#### REPORTS

The REPORTS function 1008 provides the trainer with the ability to generate numerous reports relating to the status and progress of individual participants. Its sub-functions include Active Participants List 1040, Inactive Participants List 1042, Participant Count 1044, Participant Status 1046, Visit Summary 1048, Complete Visit Summary 1050, Print Blank Surveys 1052, Print Survey Results 1054, and Allergy Control Company Report 1056. The

Active Participants List sub-function 1040 provides, at a glance, a listing of all active participants for that trainer. The Inactive Participants List sub-function 1042 provides, at a glance, a listing of all inactive participants for that trainer. The Participant Count sub-function 1044 provides a listing of all participants categorized according to their status. The Participant Status sub-function 1046 provides a detailed status of a selected participant. The Visit Summary sub-function 1048 provides a semi-detailed report of a particular visit for a selected participant. The Complete Visit Summary sub-function 1050 provides a more detailed report of a particular visit for a selected participant. The Print Blank Surveys sub-function 1052 allows the trainer to obtain unanswered hardcopies of the surveys used in the IACT program. The Print Survey Results sub-function 1054 allows the trainer to obtain hardcopies of completed surveys for a selected participant. The Allergy Control Company Report sub-function 1056 provides a report of local allergy control companies, their contact information, and the goods or services they provide.

#### UTILITIES

The UTILITIES function 1010 gives the trainer the ability to edit or modify certain data. Its sub-functions include Change Password 1058, Edit Trainer Information 1060, Edit Physician Information 1062, Edit Personal Information 1064, Change Medications 1068, Order Supplies 1070, Maintain Allergy Control Companies List 1072, and Provide Feedback 1074. The Change Password sub-function 1058 allows the trainer to change the password that grants access to the IACT program and its associated data. It is a security feature typical of many software programs. The Edit Trainer Information sub-function 1060 allows the trainer to add, delete, or modify information pertaining to himself. The Edit Physician Information sub-function 1062 allows the trainer to add, delete, or modify information pertaining to physicians involved in the

IACT program. The Edit Personal Information sub-function **1064** allows the trainer to add, delete, or modify information pertaining to participants involved in the IACT program. The Change Medications sub-function **1068** allows the trainer to add, delete, or modify information pertaining to participants' medications. The Order Supplies sub-function **1070** allows the trainer to order additional needed materials for the IACT program. The Maintain Allergy Control Companies List sub-function **1072** allows the trainer to add, delete, or modify information pertaining to selected allergy control companies. The Provide Feedback sub-function **1074** allows participants to comment on the IACT program itself, and the asthma care management program in general.

#### POST-VISIT

The POST-VISIT function **1012** manages many of the data exchange sub-functions of the IACT program. Its sub-functions include Daily Update **1076**, Add Homework Notes to Visit **1078**, Add Physician Notes to Visit **1080**, and Add Personal Notes to Visit **1082**. The Daily Update sub-function **1076** allows the trainer to synchronize, usually via a secure modem connection, the data resident on the trainer's computer and the data in the central database. The Add Homework Notes to Visit sub-function **1078** provides a checklist of items to be addressed between visits and a mechanism for appending the items to a current visit summary. The Add Physician Notes to Visit sub-function **1080** provides a blank window for inputting physician notes and appending same to a visit summary. The Add Personal Notes to Visit sub-function **1082** provides a blank window for inputting personal notes and appending same to a visit summary.

#### HELP

The HELP function 1014 provides information about the IACT computer program to the trainer. Its sub-functions include About IACT and Support Information. The About IACT sub-function 1084 provides information concerning the intellectual property rights claimed in the IACT computer program itself. The Support Information sub-function 1086 provides trainers with a contact when in need of technical support.

Selected sub-functions are now more fully described with reference to the screen that appears when the sub-function is selected by a user. The screens are described as well as important data fields within the screens.

#### HARDWARE AND SOFTWARE REQUIREMENTS

The present invention can be implemented in a variety of computer environments including a Local Area Network (LAN), Wide Area Network (WAN) environments, and stand-alone computers having dial-up modem capabilities. The present invention can be implemented in computer environments utilizing TCP/IP communications protocol, such as the Internet. Hardware for implementing the present invention is generally consistent with typical personal computing equipment, and does not generally require special environmental conditions other than a typical office environment. Preferably, the present invention is implemented on a laptop computer with a dial up connection for data transmission. Even more preferable is a server based processor having typical specifications and peripherals (e.g., 233 MHZ, 128 MB RAM, two 28.8 Kbps modem ports, and 100MB hard drive space) and having sufficient memory to perform all functions efficiently, and having sufficient data storage capacity. Also preferred is automatic back-up capability for data and configuration files and trackball or mouse support. The present invention may be implemented via other computing devices, including, but not limited to, mainframe computing systems, mini-computers, and lap-top computers. It is

preferable to use a high resolution color display; however, a standard personal computer monitor may be used.

The present invention may be written in various computer languages including, but not limited to, C++, Smalltalk, Java, Access, Visual Basic and other conventional programming languages such as BASIC, and FORTRAN.

The present invention runs on current standard desktop computer platforms such as, but not limited to, Windows®, Windows 95®, Windows NT®, UNIX®, and OS/2®. The present invention utilizes, in part, many standard features of current desktop configurations, such as the ability to store data locally, connect to the Internet, and display visual information.

The present invention is not limited in scope to systems, methods and computer program products for managing and training individuals suffering with asthma. The present invention may be utilized for managing and training individuals suffering from various other chronic diseases. Information particular to asthma sufferers can readily be substituted with information particular to other chronic conditions without departing from the spirit or scope of the present invention. Thus, the foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims.

In the claims, means-plus-function clause are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that

modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the appended claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

CLAIMS

What is claimed is:

1. A computer implemented system for aiding in the management of diseases comprising:
  - (a) a data entry means for collecting data pertaining to a disease sufferer's condition;
  - (b) a data storage means coupled to said data entry means for storing said collected data pertaining to one or more disease sufferers;
  - (c) a processing means coupled to said data entry means and communicable with said data storage means for processing the stored data; and
  - (d) a report output means coupled to said processing means and communicable with said data storage means for generating and outputting one or more reports from said processed data pertaining to a disease sufferer's condition.
2. The computer implemented system of claim 1 operating as a windows driven computer program loaded onto a general purpose computer.
3. The computer implemented system of claim 2 wherein said general purpose computer is a lap-top personal computer.
4. The computer implemented system of claim 2 further comprising data communications means for exchanging data between said general purpose computer and a database not resident on said general purpose computer.

5. The computer implemented system of claim 2 further comprising a database resident on said general purpose computer, wherein said windows driven computer program sends data to and receives data from said database.

6. The computer implemented system of claim 2 wherein said data entry means comprises a software implemented interactive windows forms questionnaire.

7. The system of claim 1 wherein said collected data includes physical data, environmental data, psychological data, environmental symptom impact data, medical diagnostic data, disease awareness, and lifestyle data about a participant.

8. A computer implemented method for aiding in the management of diseases comprising the steps of:

- (a) surveying one or more disease sufferers with respect to their condition;
- (b) entering the surveyed data into a computer;
- (c) processing the entered data in order to generate one or more reports pertaining to a disease sufferer's condition; and
- (d) outputting one or more reports in human readable form detailing a disease sufferer's condition.

9. The method of claim 8 wherein steps (a) - (d) are repeated on an as needed basis.

10. The method of claim 8 wherein said surveying step inquires as to a disease sufferer's physical condition, psychological condition, environmental

symptom impact data, medical diagnostic data, educational awareness of their disease, and lifestyle data.

11. The method of claim 8 further comprising the step of outputting educational displays and reports based upon a disease sufferer's level of educational awareness of their disease.

12. The method of claim 8 further comprising the step of tracking said disease sufferer's condition by comparing current reports to previous reports to determine any changes to said disease sufferer's condition.

13. A computer implemented method for assisting respiratory specialists in the education, training, evaluation, and management of asthma, said method comprising the steps of:

- (a) initially surveying at least one asthma sufferer with respect to physical assessments, psychological assessments, environmental assessments, educational awareness, asthma triggering stimuli, and lifestyle data as they affect their asthma condition;
- (b) inputting the surveyed data into a computer;
- (c) processing the input data in order to generate one or more reports pertaining to the asthma sufferer's current condition and their knowledge with respect to asthma;
- (d) outputting the one or more reports;
- (e) conducting follow-up visits with the asthma sufferer for the purpose of collecting respiratory diagnostic data and additional survey data pertaining to physical assessments, psychological assessments, environmental assessments, educational

awareness, asthma triggering stimuli, and lifestyle data as they affect the asthma condition;

- (f) inputting said respiratory diagnostic data and additional survey data into said computer;
- (g) processing the input data from step (f) in order to generate one or more reports pertaining to said asthma sufferer's current condition and knowledge with respect to said asthma condition; and
- (h) outputting the one or more reports pertaining to said asthma sufferer's current condition and progress since a previous visit.

14. The method of claim 13 wherein steps (e) - (h) are repeated on an as needed basis.

15. A data processing system for assisting a respiratory specialist in collecting, processing, and disseminating data for one or more asthma suffering participants pertaining to said participants' condition comprising:

- (a) data input means for collecting data pertinent to the participants' condition;
- (b) data storage and processing means coupled to said data input means for processing and storing said collected data; and
- (c) data output means coupled to said data processing means for outputting data pertinent to said participants condition and any perceivable changes therein or significant observations thereof.

16. The data processing system of claim 15 further comprising:  
(d) communication means within said data processing system coupled to said data storage and processing means for

exchanging data between said data processing system and a database.

17. The data processing system of claim 15 wherein said data input means comprises:

- (e) software based interactive forms input means executing on said data processing system for inputting and editing data pertaining to said participants;
- (f) software based interactive forms input means executing on said data processing system for inputting and editing data pertaining to participants' physicians;
- (g) software based interactive forms input means executing on said data processing system for inputting and editing data pertaining to said respiratory specialist;
- (h) software based interactive questionnaire means executing on said data processing system wherein said questionnaires include a plurality of queries with respect to the asthma condition of a participant prompting responses from said participant relating to physical assessments, psychological assessments, environmental assessments, educational awareness, asthma triggering stimuli, respiratory diagnostic data, and lifestyle; and
- (i) means for entering questionnaire responses into the data processing system's storage and processing means.

18. The data processing system of claim 15 wherein said data output means comprises:

- (k) software based report generating means coupled to said data processing and storage means for generating one or more

reports with respect to a participant's condition and any perceivable changes therein or significant observations thereof including changes in environment, psychology, changes in lifestyle, effects of asthma triggering stimuli, and changes in respiratory diagnostic data readings.

19. The data processing system of claim 15 wherein said data storage and processing means comprises:

- (l) interactive recruitment/enrollment/disenrollment means for guiding said respiratory specialist in the recruitment, enrollment, and disenrollment of participants;
- (m) interactive scheduler means for scheduling visits between the respiratory specialist and participant and maintaining the schedule of the respiratory specialist;
- (n) interactive training aid means for participant instruction in and use of nebulizers, peak flow meters, and metered dose inhalers (MDI);
- (o) interactive medication maintenance means for inputting, editing, and maintaining participant medication data; and
- (p) interactive journal means for inputting and maintaining participant notes and observations on a day-to-day basis with respect to asthma events.

20. A computer implemented process for training disease afflicted participants in the management of their diseases, said process comprising the steps of:

- (a) collecting participant demographic information;
- (b) collecting participant physical assessment information;

- (c) collecting participant environmental assessment information;
- (d) collecting participant disease triggering stimuli information;
- (e) collecting participant lifestyle assessment information;
- (f) collecting participant medical diagnostic information;
- (g) storing said collected information;
- (h) processing said stored information;
- (i) generating at least one report from said processed information;  
and
- (j) outputting said generated report.

21. The process of claim 20 wherein steps (a) - (j) are repeated on a periodic basis.

22. The process of claim 21 further comprising the step of tracking the progress of the training in and management of a chronic disease by comparing previous reports with current reports and determining any changes to a participant's condition.

23. A computer readable medium having thereon the computer implemented system of claim 1.

24. A computer readable medium having thereon the data processing system of claim 15.

25. A computer readable medium having thereon the data processing system of claim 16.

27

26. A computer readable medium having thereon the data processing system of claim 17.

27. A computer readable medium having thereon the data processing system of claim 18.

28. A computer readable medium having thereon the data processing system of claim 19.

1/6

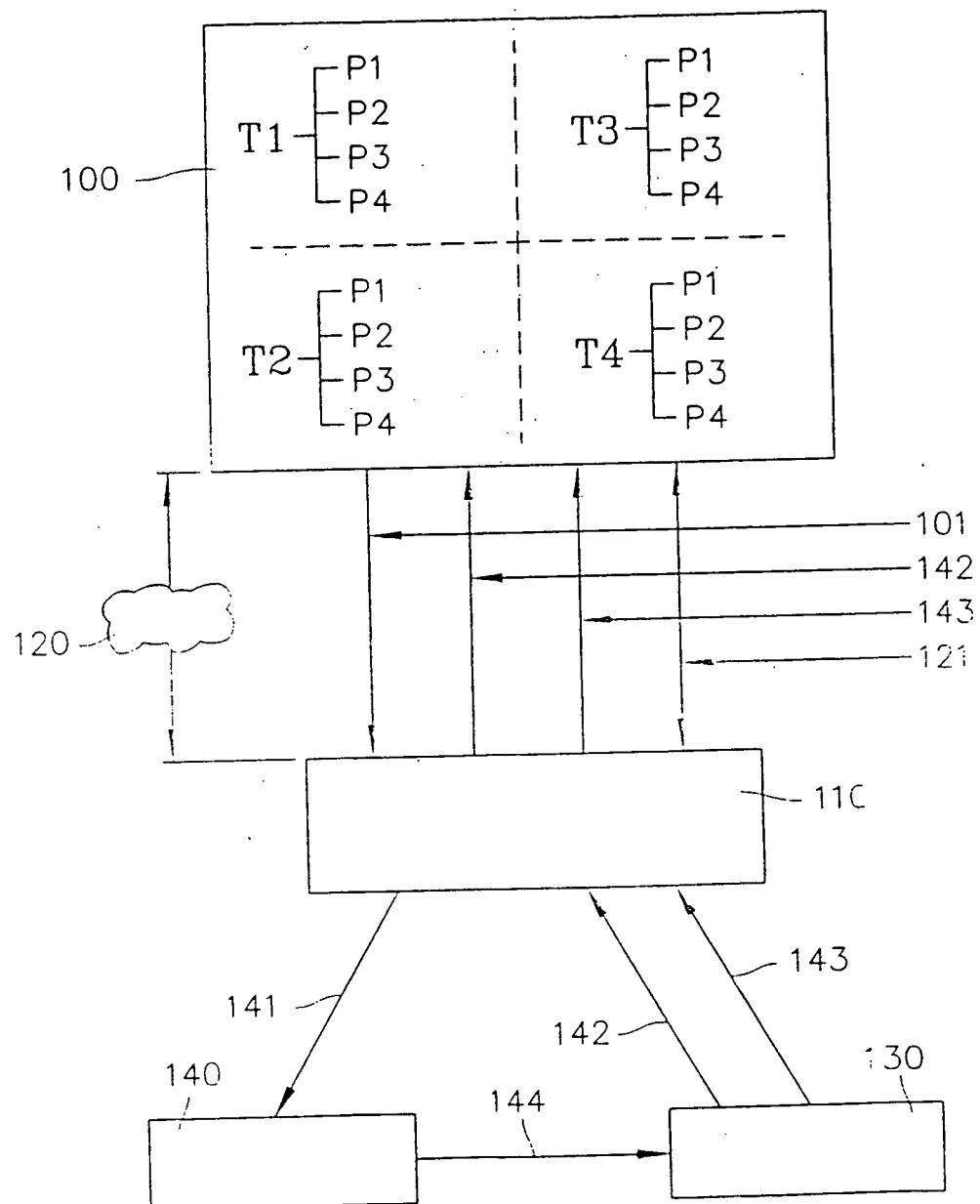


FIG. 1

2/6

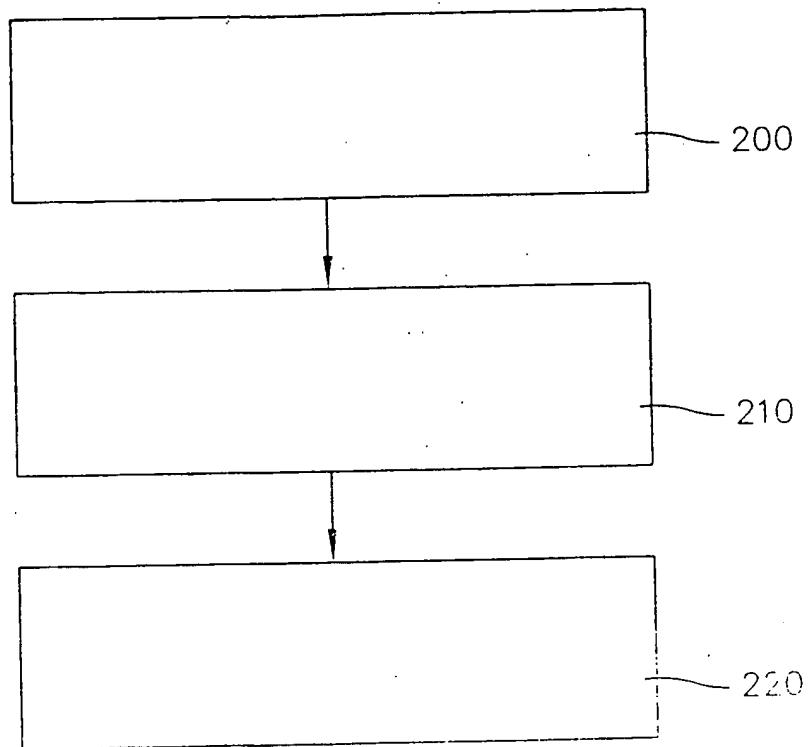


FIG.2

3/6

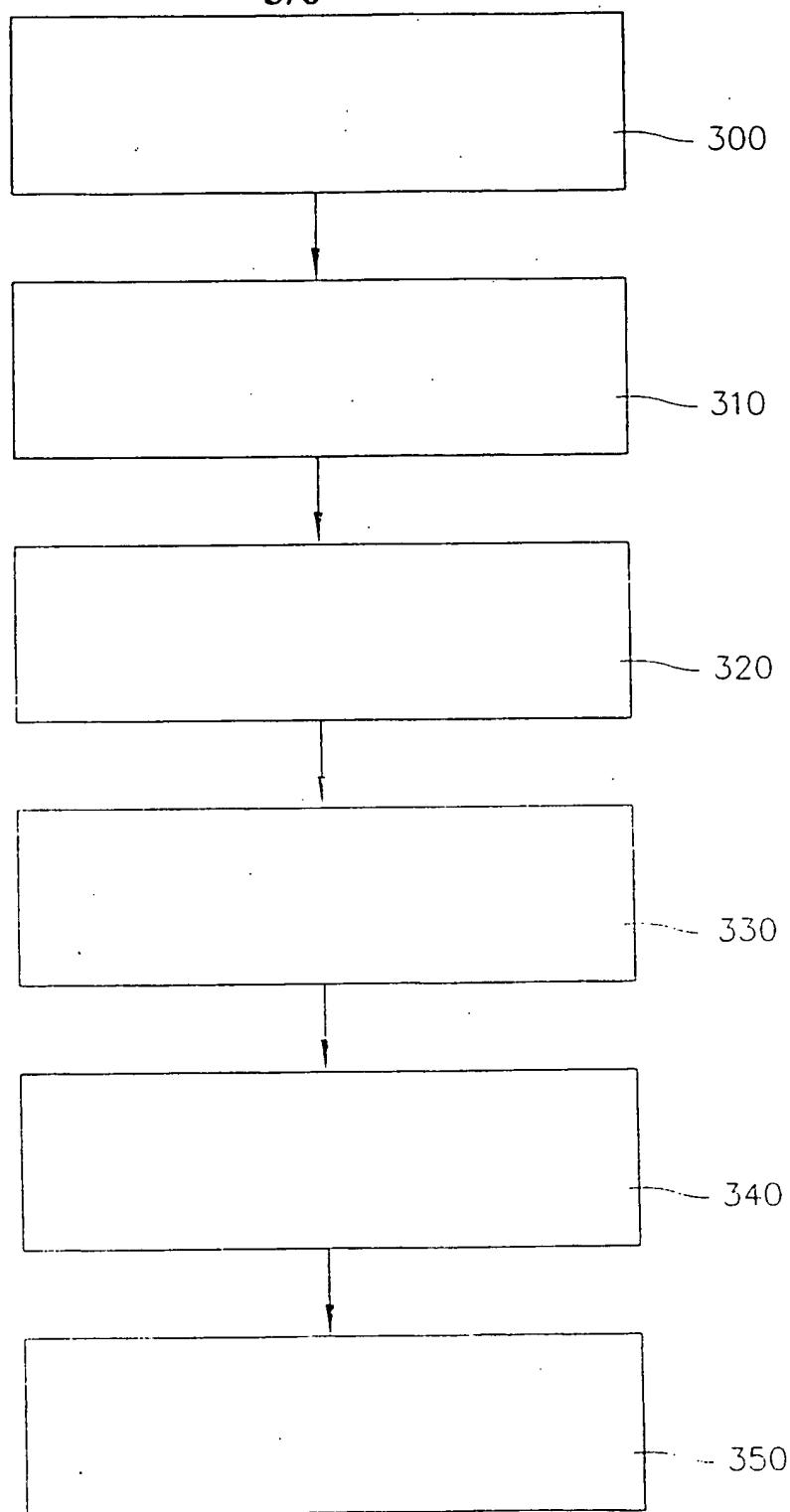


FIG.3

4/6

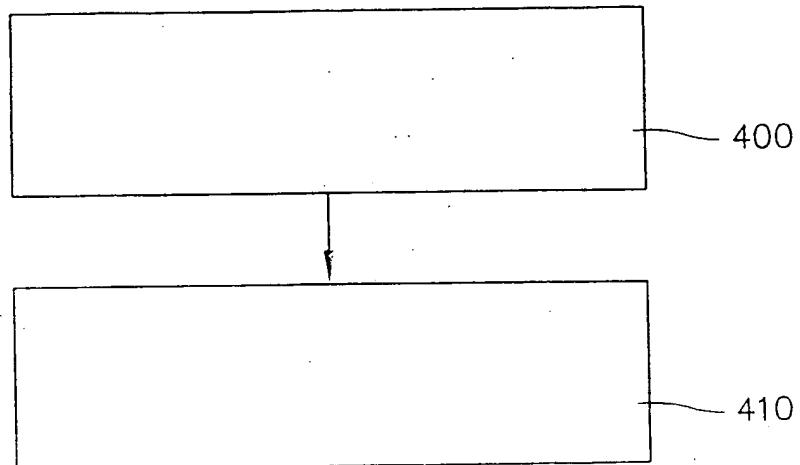


FIG 4

5/6

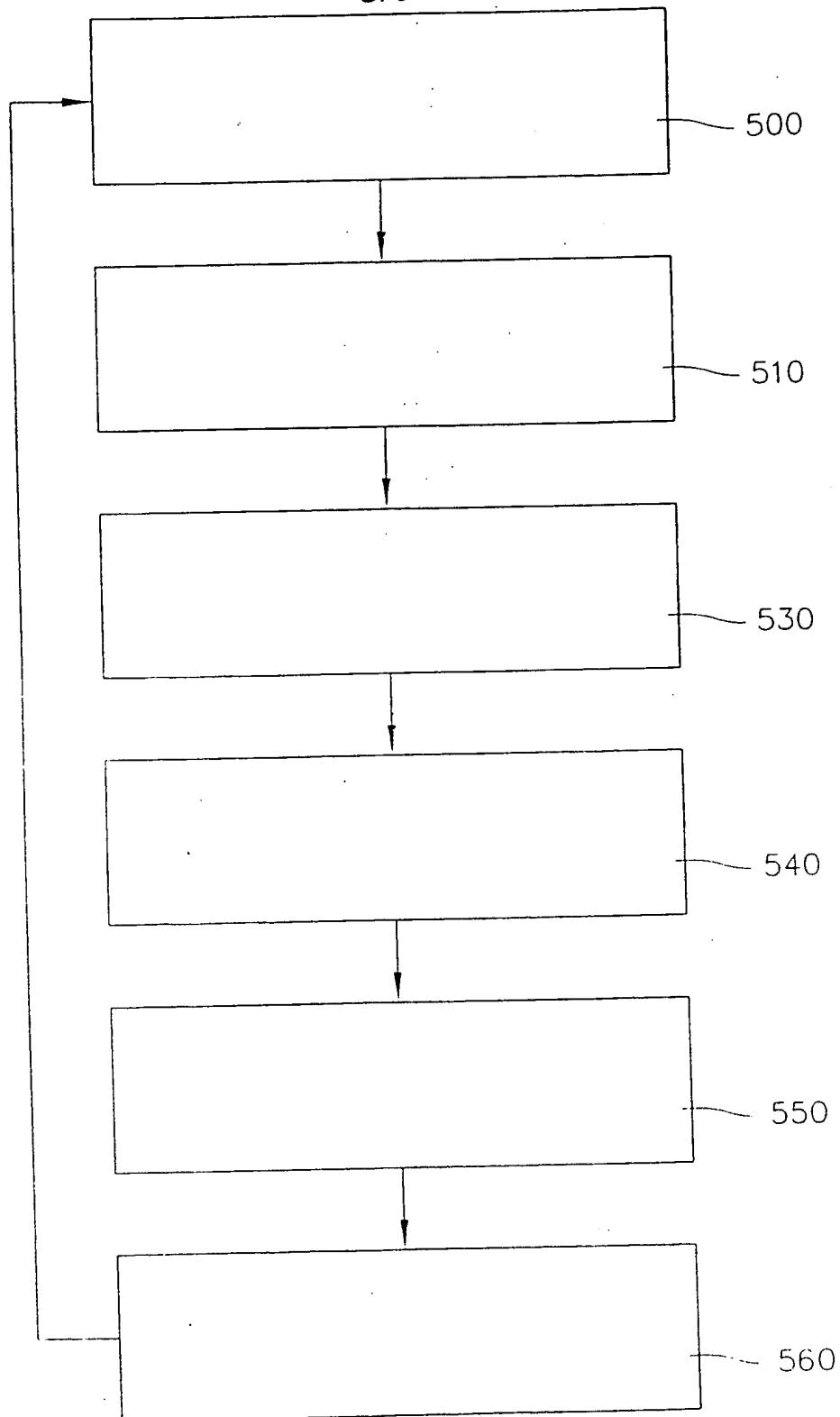


FIG. 5

6/6

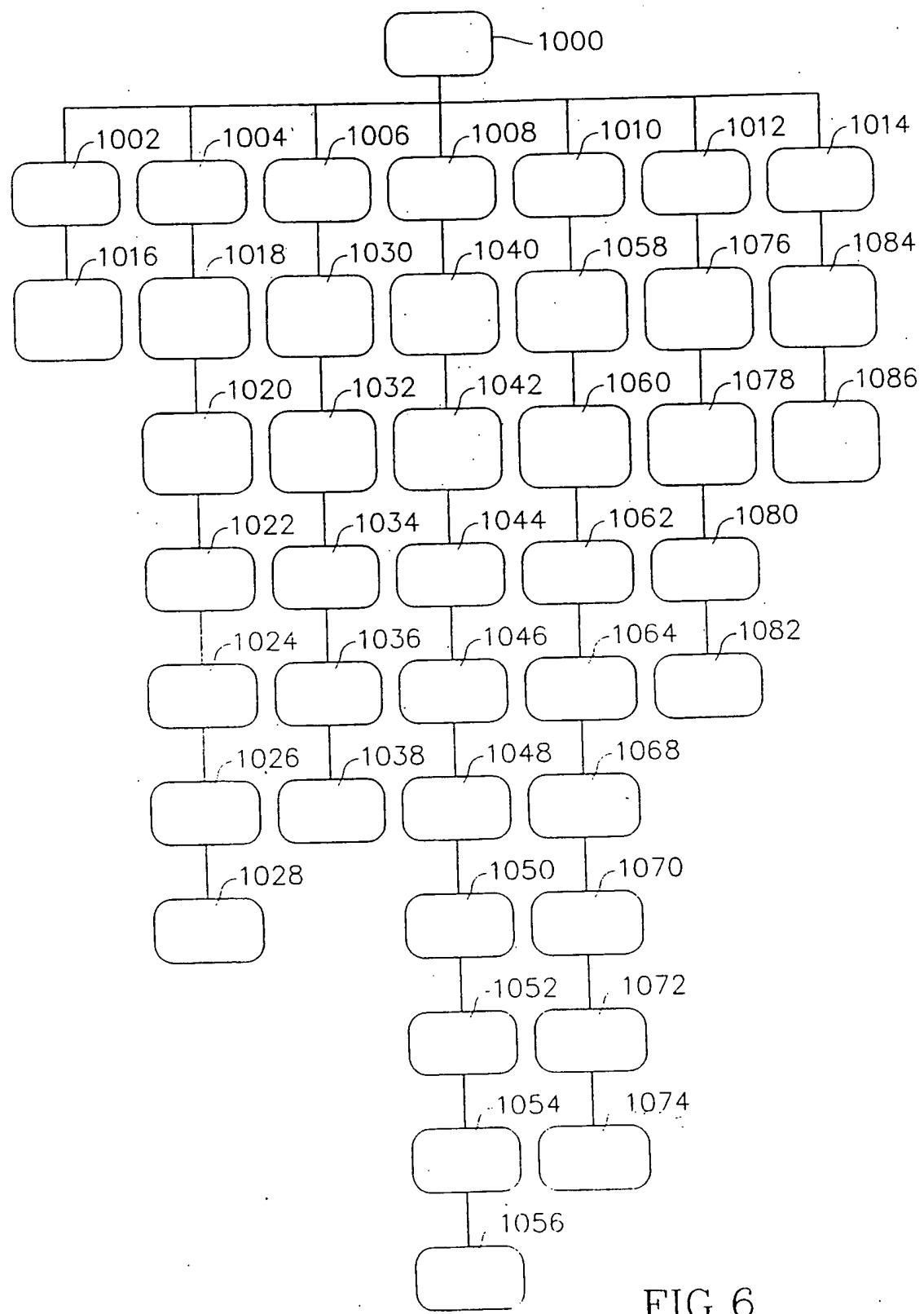


FIG. 6

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/12722

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) A61B 19/00

US CL 600/300

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. 128/920-924; 434/262; 600/300

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,678,571 A (BROWN) 21 October 1997, entire document.	8-14, 20-22
X,P	US 5,827,180 A (GOODMAN) 27 October 1998, entire document.	8-14, 20-22
X,P	US 5,897,493 A (BROWN) 27 April 1999, entire document.	8-14, 20-22
X	US 5,711,207 A (ILIFF) 27 January 1998, entire document.	8-14, 20-22



Further documents are listed in the continuation of Box C.



See patent family annex.

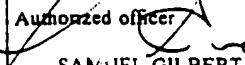
* Special categories of cited documents	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

28 JULY 1999

Date of mailing of the international search report

02 SEP 1999

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231  
Facsimile No. (703) 305-3230Authorized officer  
  
SAMUEL GILBERT

Telephone No. (703) 308-3553

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US99/12722

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 1-7, 15-19, 23-28  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
The claims are directed to a computer program.
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.